S-1155.1

SENATE BILL 5700

State of Washington 63rd Legislature 2013 Regular Session

By Senators Conway, Keiser, Parlette, and Pearson

Read first time 02/11/13. Referred to Committee on Health Care .

AN ACT Relating to regulating pharmacy benefit manager audit procedures; reenacting and amending RCW 18.64.011; adding a new section to chapter 18.64 RCW; and creating a new section.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

Sec. 1. RCW 18.64.011 and 2009 c 549 s 1008 are each reenacted and amended to read as follows:

Unless the context clearly requires otherwise, definitions of terms shall be as indicated when used in this chapter.

(1) "Administer" means the direct application of a drug or device, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject.

(2) "Board" means the Washington state board of pharmacy.

(3) "Compounding" shall be the act of combining two or more ingredients in the preparation of a prescription.

(4) "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of chapter 69.50 RCW.

(5) "Deliver" or "delivery" means the actual, constructive, or

attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

(6) "Department" means the department of health.

(7) "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals, or (b) to affect the structure or any function of the body of human beings or other animals.

(8) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

(9) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(10) The words "drug" and "devices" shall not include surgical or dental instruments or laboratory materials, gas and oxygen, therapy equipment, X-ray apparatus or therapeutic equipment, their component parts or accessories, or equipment, instruments, apparatus, or contrivances used to render such articles effective in medical, surgical, or dental treatment, or for use or consumption in or for mechanical, industrial, manufacturing, or scientific applications or purposes, nor shall the word "drug" include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended, nor medicated feed intended for and used exclusively as a feed for animals other than human beings.

(11) "Drugs" means:

(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals;

(c) Substances (other than food) intended to affect the structure or any function of the body of human beings or other animals; or

(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

(12) "Health care entity" means an organization that provides health care services in a setting that is not otherwise licensed by the

state. Health care entity includes a freestanding outpatient surgery center or a freestanding cardiac care center. It does not include an individual practitioner's office or a multipractitioner clinic.

(13) "Labeling" shall mean the process of preparing and affixing a label to any drug or device container. The label must include all information required by current federal and state law and pharmacy rules.

(14) "Legend drugs" means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(15) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages, or labels such substance or device.

(16) "Manufacturer" shall mean a person, corporation, or other entity engaged in the manufacture of drugs or devices.

(17) "Master license system" means the mechanism established by chapter 19.02 RCW by which master licenses, endorsed for individual state-issued licenses, are issued and renewed utilizing a master application and a master license expiration date common to each renewable license endorsement.

(18) "Nonlegend" or "nonprescription" drugs means any drugs which may be lawfully sold without a prescription.

(19) "Person" means an individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(20) "Pharmacist" means a person duly licensed by the Washington state board of pharmacy to engage in the practice of pharmacy.

(21) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted.

(22) The word "poison" shall not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended.

(23) (a) "Pharmacy benefits management" means the procurement of prescription drugs at a negotiated rate for dispensation within Washington state to covered individuals, the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals, or any of the following services provided with regard to the administration of pharmacy benefits:

(i) Mail-order pharmacy;

(ii) Claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;

(iii) Clinical formulary development and management services;

(iv) Rebate contracting and administration;

(v) Certain patient compliance, therapeutic intervention, and generic substitution programs; and

(vi) Disease management programs.

(b) "Pharmacy benefits management" does not include activities of retail, community, long-term care, or hospital pharmacies licensed under this chapter that are not carried out as part of a contract entered into by that pharmacy with a covered entity to administer and manage payment for pharmacy benefits for covered individuals.

(24) "Pharmacy benefits manager" means an entity that performs pharmacy benefits management. "Pharmacy benefits manager" includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity and includes mail-order pharmacy. "Pharmacy benefit manager" does not include a health carrier as defined in RCW 48.43.005 if the health carrier provides or administers pharmacy benefits management to its insureds, participants, members, or enrollees, or pharmacy operations of any integrated delivery system undertaken for the benefit of patients obtaining care through that system.

(25) "Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice

by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

((~~(24)~~)) (26) "Practitioner" means a physician, dentist, veterinarian, nurse, or other person duly authorized by law or rule in the state of Washington to prescribe drugs.

((~~(25)~~)) (27) "Prescription" means an order for drugs or devices issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

((~~(26)~~)) (28) "Secretary" means the secretary of health or the secretary's designee.

((~~(27)~~)) (29) "Wholesaler" shall mean a corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

NEW SECTION. **Sec. 2.** A new section is added to chapter 18.64 RCW to read as follows:

(1) Any contract between a pharmacy benefits manager and a pharmacy must include procedures on auditing of claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to covered individuals.

(2) The pharmacy benefits manager or entity designated by the pharmacy benefits manager conducting an audit must:

(a) Provide the pharmacy that is the subject of the audit at least fourteen days written notice before conducting an initial audit;

(b) If the audit involves clinical or professional judgment, consult with or have the audit conducted by a pharmacist licensed in the state of the audit or the state board of pharmacy;

(c) Only audit claims submitted within two years from the date of the audit;

(d) Choose a mutually acceptable date on which to conduct the audit;

(e) If necessary, use the records of a hospital, institution,

prescriber, or other health care provider to verify the pharmacy record;

(f) If necessary, use any prescription or medication order to verify claims in connection with prescriptions, refills, or changes in prescriptions;

(g) Audit a pharmacy using the same standards and parameters as other similarly situated pharmacies;

(h) Establish a written appeals process. The appeals process must include appeals of preliminary reports. If either party is not satisfied with the final report, that party may seek mediation or arbitration;

(i) Determine a finding of overpayment, if any, based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs;

(j) Not include dispensing fees in calculations of overpayments;

(k) Not receive payment based on a percentage of the amount recovered;

(l) Accrue interest on overpayments during the audit period or the appeals process; and

(m) Not subject the pharmacy to recoupment of funds if the audit results in the identification of any clerical or recordkeeping discrepancies in a required document or record, unless it can be shown that the discrepancies result in actual financial harm to the pharmacy benefits manager, a health plan managed by the pharmacy benefits manager, or a consumer.

(3) Audit information and reports must be provided according to the following:

(a) A pharmacy benefits manager or entity designated by the pharmacy benefits manager that conducts an audit of a pharmacy must provide the pharmacy with a preliminary audit report, delivered to the pharmacy or its corporate office of record within sixty calendar days after completion of the audit;

(b) A pharmacy must be allowed at least forty-five calendar days or other mutually agreeable time frame following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit;

(c) A final audit report must be delivered to the pharmacy within ninety calendar days after receipt of the preliminary audit report or final appeal, whichever is later;

(d) No charge backs, recoupment, or other penalties may be assessed until the appeal process has been exhausted and the final report issued;

(e) Audit information may not be shared. Auditors only are permitted access to previous audit reports on a particular pharmacy conducted by that same entity.

(4) The pharmacy benefits manager must provide a copy of the final report, including disclosure of any money recouped in the audit to the plan sponsor.

NEW SECTION. **Sec. 3.** This act applies to contracts between pharmacy benefits managers and pharmacies entered into, amended, extended, or renewed on or after January 1, 2014.

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